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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,682	03/30/2001	Michael Streit	10287-051002 / MGH 1470.2	9232
26161	7590	11/25/2003	EXAMINER YU, MISOOK	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ART UNIT 1642	PAPER NUMBER
DATE MAILED: 11/25/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,682

Applicant(s)

STREIT ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-73, 75-79 and 81-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-73, 75-79 and 81-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Interview Summary, page 1 of declaration

DETAILED ACTION

Applicant's amendment, IDS, and Dr. Detmar's declaration (Paper No. 22) filed on 5 September 2003 are acknowledged. The Dr. Detmar's declaration filed on 5 September 2003 will not be considered in this Office action because it is not clear at this time whether the declaration was intended for the instant application or application with 09/536,087. The Office's record shows that the attorney docket number for the instant application is 10287-051002/MGH 1470.2 as it appears on the declaration. However, the serial number on the declaration does not match with the instant application number. Note the attached page 1 of the declaration.

Claims 54, 55, 57, 75, 81, 82 are amended, and claims 86-99 are newly presented. Claims 54-73, 75-79, and 81-99 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

It appears that the specification for another related application filed as a copy of IDS filed on 11-25-2002 has been treated by the Office as a substituted specification (Paper No. 16) for the instant application. The title of the other application is "Delivery of the Thrombospondin from implantable tissue matrices". From the list and copy of the IDS filed on November 19, 2002, it is not clear the application titled "Delivery of the Thrombospondin from implantable tissue matrices" was a substitute specification for the instant application or a copy of IDS. When applicant confirms the application titled "Delivery of the Thrombospondin from implantable tissue matrices" was a copy of IDS

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filed on 11-25-2002, then this objection will be withdrawn and the record of Office will be corrected.

Claim Rejections - 35 USC § 112

Enablement

Claims 54-73, 75-79, and 81-85 **remain rejected** for reason of record and the new claims 86-98 are also rejected under rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 54-73, 75-79, and 81-98 are drawn to method of treating an angiogenesis-dependent tumor by administering a cell expressing a protein 95-100 % identical to SEQ ID NO:2 (claims 54-73, 75-79, 82-98) or cell expressing a protein from a nucleic acid hybridizes to SEQ ID NO:1 under the specified condition (claim 82), or a fragment thereof capable of inhibiting endothelial migration, wherein said fragment comprises at least 10 contiguous amino acids either a procollagen domain of TSP-2 or a type I repeat of TSP-2.

Applicant argues: the present claims are drawn to narrower scope by reciting specific structures of TSP-2, which have been shown to work in the claimed method and making various fragments or mutations in a known protein is a routine molecular biology technique; the first Dr. Detmar's declaration and Streit reference support enablement; the claims cover ex-vivo cell therapy methods, not in vivo gene therapy; the claimed

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methods work to inhibit tumor growth. The arguments have been fully considered but found unpersuasive for the following reasons:

The base claims 54, 81, and 82 require making a construct expressing a TSP-2 fragment capable of inhibiting endothelial migration, wherein said fragment comprises **at least 10 contiguous amino acids either a procollagen domain of TSP-2** or a type I repeat of TSP-2 for the purpose stated in the preamble of the claims. Compare the bold-faced limitation in the base claims and the data in Fig. 7, which shows Peptide 7 (first type 1 repeat) as the only peptide capable of inhibiting endothelial migration and the rest of peptides comprising at least 10 contiguous amino acids of a procollagen domain of TSP-2 do not have the recited function according to second paragraph at page 45. The specification does not provide guidance how to make a fragment thereof capable of inhibiting endothelial cell migration, wherein said fragment comprises at least 10 contiguous amino acids of a procollagen domain of TSP-2 let alone how to use said fragment in method of treating a tumor.

The argument with data shown at Fig. 3 of the specification and that data shown in the first Dr. Declaration is not commensurate in scope of the claims because the claims are **not limited** to a construct expressing SEQ ID NO:2 or the specific fragment in the declaration. The specification does not teach how to make and use the various products for unpredictable cancer treatment, for example a construct expressing fragment comprising at least 10 contiguous amino acids either a procollagen domain of TSP-2. The specification does not teach any cell therapy for cancer treatment method

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using a construct expressing a fragment comprising at least 10 contiguous amino acids a procollagen domain of TSP-2.

Considering unpredictability in the cancer treatment art, broad scope of claims, insufficient guidance with regard using various claimed products to accomplish the purpose stated in the preamble of the claims, it is maintained that undue experimentation would be required to practice the invention as claimed.

New matter

Claims 54-73, 75-79, and 81-99 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, the base claims recite "an angiogenesis-dependent tumor". Applicant stated in the amendment that the specification at page 2 lines 19-24, page 23 lines 8-10, "pages 33 lines 28 to page 31, line 2" and the original claims. However, although the specification at page 2 line 19-24 and the original claims have support for unwanted cell proliferation, unwanted angiogenesis, benign or malignant unwanted cell proliferation, it does not have support new limitation "an angiogenesis-dependent tumor". The specification at pages 33 lines 28 to page 31, line 2 contemplates usefulness of the fragments of SEQ ID NO: 2 in cancer treatment but do not support the new limitation "an angiogenesis-dependent tumor", either.

Second, "at least 10 contiguous amino acids of a procollagen domain" recited in the base claims 54, 81, and 82 are not supported by the specification or claims as filed.

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The specification states on page 23 that a fragment of TSP-2 can be at least 10 amino acids in length and contain a type 1 repeat. Applicant states on page 9 of the response that "at least one fragment having a portion of a procollagen domain of TSP-2 is disclosed". However, the disclosure of a single fragment comprising a portion of a procollagen domain is not the basis for a genus of fragments comprising at least 10 contiguous amino acids of the procollagen domain.

Conclusion

All other rejections and objections of prior record not repeated in this Office action are withdrawn.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-

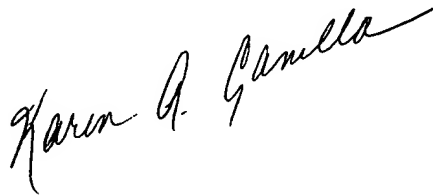
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308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
November 24, 2003

A handwritten signature in cursive script, reading "Karen A. Gamella". The signature is written in dark ink and is slanted upwards to the right.